

SAFETY DATA SHEET

PoliDent

according to Commission Regulation (EU) 2020/878 as amended



X-RAY CAD-CAM DISC

Creation date	21st November 2019	Version	2.0
Revision date	27th February 2023		

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- 1.1. Product identifier** X-RAY CAD-CAM DISC
Substance / mixture mixture
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
X-ray visible disc used for milling diagnostic stents for implant planning.
Mixture uses advised against
The product should not be used in ways other than those referred in Section 1.
- 1.3. Details of the supplier of the safety data sheet**
Manufacturer
Name or trade name Polident d.o.o., Dental Products Industry
Address Volčja Draga 42, Volčja Draga, 5293
Slovenia
VAT Reg No SI31319297
Phone 00386 5 3304840, Fax: 00386 5 3304870
E-mail polident@polident.si
- Competent person responsible for the safety data sheet**
Name Polident d.o.o., Dental Products
Industry Industry
E-mail polident@polident.si
- 1.4. Emergency telephone number**
00386 5 3304840 - Polident d.o.o. - Available from Mon to Fri 7 a.m. to 3 p.m.
112 - Information center - available 0-24

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**
Classification of the mixture in accordance with Regulation (EC) No 1272/2008
The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008.
Full text of all classifications and hazard statements is given in the section 16.
- 2.2. Label elements**
none
- 2.3. Other hazards**
The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

SECTION 3: Composition/information on ingredients

- 3.2. Mixtures**
Chemical characterization
Material based on polymethylmethacrylate with barium sulfate.
Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment
none

SECTION 4: First aid measures

- 4.1. Description of first aid measures**
Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.
If inhaled
Remove the casualty into fresh air. In case of complaints get medical advice.
If on skin
Wash off with water and soap. Consult a physician if irritation persists.

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If in eyes

There are not any particular first aid measures required. When dust comes into contact with the eyes wash eyes immediately with running water; if the affected person wears contact lenses, remove them immediately. Depending on the situation, call medical rescue service or ensure medical treatment.

If swallowed

Not likely. Wash out mouth with water and drink water. In case of complaints get medical advice.

4.2. Most important symptoms and effects, both acute and delayed

If inhaled

Not expected.

If on skin

Not expected.

If in eyes

Not expected.

If swallowed

Not expected.

4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist. Accommodate extinguishing components to the location of fire.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage. Burning or thermal decomposition produces toxic, irritating and flammable fumes.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with gas-tight suit when close proximity to the substance or its vapours is likely. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Follow the instructions in the Sections 7 and 8.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

Pick up the product mechanically. Dispose of the collected material according to the instructions in the section 13.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Only adequate trained persons may deal with product. For use in dentistry only.

Use personal protective equipment as per Section 8. Keep out of reach of children. Do not eat, drink or smoke when using this product. Ensure the area is well ventilated.

7.2. Conditions for safe storage, including any incompatibilities

Store the product only in its original packaging. Store in a dry place.

7.3. Specific end use(s)

not available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The mixture contains no substances for which occupational exposure limits are set.

8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest. Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation.

Eye/face protection

Not required under normal circumstances. We recommend the use of safety glasses during mechanical processing.

Skin protection

Hand protection: protective gloves that protect against mechanical particles.

Respiratory protection

Under regular circumstances it is not necessary.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	solid
Colour	white
Odour	without fragrance
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available
Lower and upper explosion limit	data not available
Flash point	>250 °C
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	insoluble
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

When used in the standard way, there is not any dangerous reaction with other substances. Depolymerization starts at 250 °C.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

The product is stable under normal conditions. According to the instructions for use, there are no known dangerous reactions.

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10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost. Avoid heating above 240 °C.

10.5. Incompatible materials

No information.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire. Organic products.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

No toxicological data is available for the mixture.

Acute toxicity

Based on available data the classification criteria are not met.

Skin corrosion/irritation

Based on available data the classification criteria are not met.

Serious eye damage/irritation

Based on available data the classification criteria are not met.

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Carcinogenicity

Based on available data the classification criteria are not met.

Reproductive toxicity

Based on available data the classification criteria are not met.

Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

Aspiration hazard

Based on available data the classification criteria are not met.

11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information

12.1. Toxicity

Acute toxicity

No other relevant information is available, no evidence of hazardous properties.

12.2. Persistence and degradability

No other relevant information is available, no evidence of hazardous properties.

12.3. Bioaccumulative potential

No other relevant information is available, no evidence of hazardous properties.

12.4. Mobility in soil

No other relevant information is available, no evidence of hazardous properties.

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

No information.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of waste in accordance with local and/or state regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity.

Waste management legislation

Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (S.I. No. 871 of 2007).
Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended.
Decision 2000/532/EC establishing a list of wastes, as amended.

SECTION 14: Transport information

14.1. UN number or ID number

not subject to transport regulations

14.2. UN proper shipping name

not relevant

14.3. Transport hazard class(es)

not relevant

14.4. Packing group

not relevant

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Clean Air Act 1993 as amended.

The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 as amended.

Public health act 1961.

Environmental Protection Act 1990 as amended.

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended.

Product is a medical device class I according to the Medical Device Regulation MDR 2017/745.

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: Other information

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures

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EC	Identification code for each substance listed in EINECS
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
log Kow	Octanol-water partition coefficient
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

The version 2.0 replaces the SDS from 21.11.2019

Changes were made in sections:

- 2.2. Label elements,
- 2.3 Other hazards,
- 11.2 Information on other hazards,
- 12.6 Endocrine disrupting properties and
- 16 Other information.

More information

Classification procedure - calculation method.

Safety Data Sheet created by CHEM CONSULTING s.p. (info@chem-consulting.si).

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.